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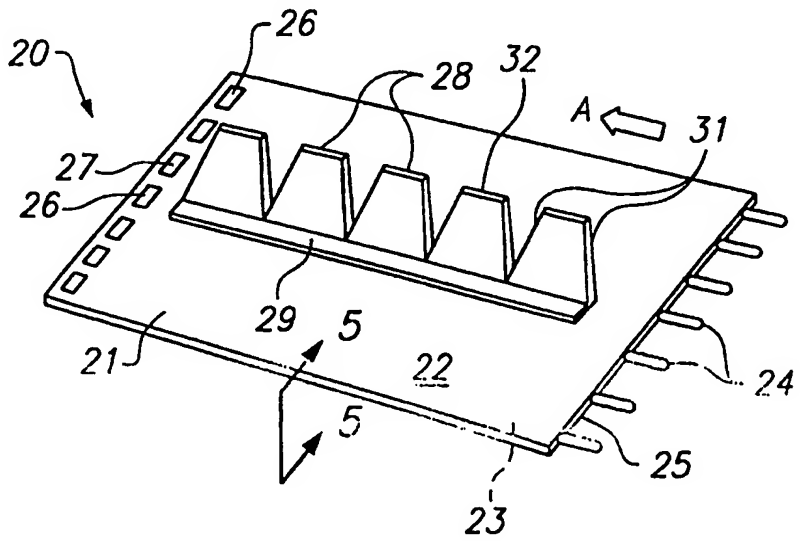
(54) Title: COILED SHEET VALVE, FILTER OR OCCLUSIVE DEVICE AND METHODS OF USE

(57) Abstract

Apparatus (20) is provided comprising a coiled sheet (21) having a plurality of flaps (28) mounted on its interior surface that project radially inward into a lumen (30) formed by the interior surface of the apparatus when it is deployed. The flaps (28) lie parallel to the interior surface of the sheet during transluminal delivery, but project radially inward once the apparatus (20) is deployed. The flaps (28) may comprise a fine mesh for uses as a filter, or alternatively may be covered with a biocompatible material that is substantially impermeable, so as to partially or completely occlude the lumen (30). In a further alternative embodiment, the flaps (28) may comprise a resilient biocompatible plastic or polymer, so that the flaps (28) move in response to the flow, and function as a pressure–based or directional valve.



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COILED SHEET VALVE, FILTER OR OCCLUSIVE DEVICE AND METHODS OF USE

Field Of The Invention

The present invention relates generally to minimally-invasive techniques and apparatus for implanting a filter, valve or occlusive device in a hollow-body organ or vessel.

Background Of The Invention

In recent years a need has arisen for filters, valves and occlusive devices that may be implanted percutaneously and transluminally. Such devices may be used either to filter particulate matter from a fluid flow, to regulate the fluid flow, or to partially or completely occlude the flow.

A number of devices are known for trapping particulate matter downstream of the site of a therapeutic procedure, e.g., angioplasty, to reduce embolization of materials following completion of the procedure. U.S. Patent No. 4,723,549 to Wholey et al. describes a filter basket disposed from an angioplasty device to collect and trap frangible material liberated during an angioplasty procedure. U.S. Patent No. 4,425,908 describes an implantable self-expanding

filter basket formed of a plurality of nickel-titanium wires.

A number of devices also are known for occluding flow through a vessel. For example, U.S. Patent No. 5,382,261 to Palmaz is directed to a deformable slotted stent that includes a membrane disposed transverse to the flow direction to occlude the vessel. These devices may be advantageously used wherever it is desired to occlude flow, for example, through a arterio-venous fistula, or as part of the treatment of a congenital heart defect.

A number of devices also are known for regulating the flow of tissue through a body vessel or organ. U.S. Patent No. 5,655,548 to Nelson et al. describes a tubular member including a valved portion for regulating the flow through an arterio-venous passageway. U.S. Patent No. 5,409,019 to Wilk describes regulating flow through a myocardial passageway using a first embodiment comprising a multi-part rigid stent that includes valve flaps, and an alternative embodiment wherein the stent itself is biased to collapse during cardiac diastole.

A drawback of the foregoing devices is that they generally are not compatible with previously known delivery devices, and require special handling for optimum performance. In addition, such devices have a limited range of applications in which they may be employed. Specifically, the ability to deliver such devices to small diameter vessels depends on the specific configuration of the device and its intended purpose.

A stent design particularly well suited for use as a base for a filter, valve or occluder is the coiled sheet stent of the type described in U.S. Patent No. 5,007,926 to Derbyshire, and U.S. Patent No. 5,443,500 to Sigwart, which are incorporated herein by reference. A coiled sheet stent generally comprises a flat relatively flexible mesh, and may have teeth on one edge and openings that accept the teeth on the opposing edge. The stent is formed by rolling the mesh into a tube, with the edge oriented inside and aligned with the axis of the tube. The stent generally is formed of a resilient material, such as stainless steel or a nickel-titanium alloy, and may be designed to be highly crush resistant.

The foregoing coiled sheet stents may be percutaneously and transluminally delivered by rolling the stent to a small diameter and inserting it into a sheath that retains the stent in the contracted state. Such a delivery system is described in U.S. Patent No. 4,665,918 to Garza et al., which is also incorporated herein by reference. Upon delivery of a coiled sheet stent to the implantation site, the constraint (e.g., sheath) is removed, and the stent is permitted to unroll. The stent may be further expanded into position using a conventional balloon dilatation device, thereby locking the teeth into engagement with the openings in the opposing edge.

In view of the foregoing, it would be desirable to provide apparatus that may be delivered using previously known delivery apparatus, and that can be delivered to small vessels and through tortuous vessel anatomy.

It further would be desirable to provide a device capable of being employed as either a filter, a valve or occluder, depending upon the desired therapeutic application.

It also would be desirable to provide a device capable of being employed in filter, valve or occluder applications that builds upon the acknowledged advantages of coiled sheet stent technology, including capability to achieve very small delivery diameters, ease of deployment, high crush resistance, and low migration potential.

Summary Of The Invention

In view of the foregoing, it is an object of this invention to provide apparatus suitable for use in filter, flow regulation, and occlusion applications that overcomes the drawbacks of previously known devices.

It is a further object of the present invention to provide apparatus that may be delivered using previously known delivery apparatus, and that can be delivered to small vessels and through tortuous vessel anatomy.

It is another object of this invention to provide a device capable of being employed as either a filter, a valve or occluder, depending upon the desired therapeutic application.

It is a still further object of the present invention to provide a device capable of being employed in filter, valve or occluder applications that builds upon the acknowledged advantages of coiled sheet stent technology, including capability to achieve very small

delivery diameters, ease of deployment, high crush resistance, and low migration potential.

These and other objects of the invention are accomplished in accordance with the principles of the invention by providing apparatus comprising a coiled sheet having a plurality of flaps mounted on its interior surface, the flaps projecting radially inward into a lumen formed by the interior surface of the apparatus when it is deployed. In accordance with the invention, the flaps lie parallel to the interior surface of the coiled sheet when the apparatus is configured for delivery, and project radially inward once the apparatus is deployed.

In one embodiment of the invention, the flaps are formed of a fine mesh, and are arranged so that the innermost ends of the tips overlap when the apparatus is deployed. The flaps may in addition be coated with an anti-thrombogenic material (e.g. heparin), for improved hemo-compatibility. In this case, the mesh serves to filter particulate matter from the flow passing through the apparatus, thus reducing the risk of embolism.

Alternatively, the flaps may be covered with a biocompatible material that is substantially impermeable. If the tips of the flaps are configured to overlap, the device may be used as an occlusive device to completely cut-off the flow through the central lumen of the apparatus. If, on the other hand, the tips of the flaps do not overlap, they may form an aperture having a reduced diameter (relative to the vessel diameter), to provide a degree of flow regulation.

In yet a further alternative embodiment, the flaps may comprise a resilient biocompatible plastic or polymer, so that the flaps move in response to the flow. In this embodiment, the flaps may advantageously serve as a valve that actively regulates flow through the vessel or organ.

In accordance with the principles of the present invention, a filter, valve or occlusive apparatus constructed in accordance with the present invention employs a coiled sheet stent as the base for delivering and implanting the device. Such stents generally have high crush resistance, and the use of interlocking teeth, as in the above-incorporated Derbyshire and Sigwart patents, reduces the risk of post implantation migration. These benefits are directly transferred to a device constructed in accordance with the present invention, as well as small delivery diameter and ease of use.

Methods for employing a device constructed in accordance with the principles of the present invention are also described.

Brief Description Of The Drawings

Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawings and the following detailed description of the preferred embodiments, in which:

FIG. 1 is a perspective view of a previously known coiled sheet stent suitable for use in constructing the apparatus of the present invention;

FIG. 2 is a perspective view of apparatus constructed in accordance with the present invention in an unrolled state;

FIG. 3 is a perspective view, partly cut-away, of the apparatus OF FIG. 2 in its deployed condition;

FIGS. 4A, 4B and 4C are sectional views showing alternative embodiments of the flaps of the present invention;

FIGS. 5A and 5B are views similar to that taken along line 5--5 of FIG. 2 illustrating alternative embodiments of the flaps of the apparatus of the present invention; and

FIGS. 6A and 6B are, respectively, an elevation view, partly in section, and cross-sectional view showing the apparatus of FIG. 2 loaded with a delivery device, while FIG. 6C illustrates a step of deploying the apparatus.

Detailed Description Of The Invention

The present invention provides apparatus capable of serving as a filter, a valve or an occlusive device which can be percutaneously and transluminally implanted within a body vessel or organ. In particular, the apparatus comprises a coiled sheet having a plurality of radially inwardly projecting flaps that project into a lumen formed in the apparatus when it is deployed. The tips of the flaps may be arranged to overlap, so that if the flaps comprise a mesh, the flaps form a filter that traps particulate matter flowing through the lumen.

Alternatively, the flaps may be covered with an impermeable biocompatible material that occludes flow through the vessel. The flaps, may also be covered with an impermeable biocompatible material and have non-overlapping tips, thereby forming an aperture

that introduces a passive flow impedance. In yet another embodiment the flaps may comprise a resilient plastic or polymer, and function as parts of a valve, thus providing active flow regulation.

Advantageously, the apparatus of the present invention may be configured to provide a variety of functions, while retaining some of the best characteristics of a coiled sheet stent, such as small delivery diameters, high crush resistance, low migration potential and ease of deployment.

Referring now to FIG. 1, a previously known coiled sheet stent 10 is described. Coiled sheet stent 10 is of the type described in U.S. Patent No. 5,007,926 to Derbyshire and U.S. Patent No. 5,443,500 to Sigwart, which are incorporated herein by reference. Coiled sheet stent 10 generally comprises a mesh formed of a flexible material such as a stainless steel or nickel-titanium alloy. Stent 10 preferably includes teeth 11 on edge 12 and openings 13 on opposing edge 14 that engage teeth 11 when the stent is deployed. Stent 10 is formed by rolling the mesh into a tube, with edge 12 positioned inside and aligned with the axis of the tube.

Stent 10 may be percutaneously and transluminally delivered by rolling the stent to a small diameter and inserting it into a sheath that retains the stent in a contracted delivery state. Such a delivery system is described in the above-incorporated Sigwart patent and in U.S. Patent No. 4,665,918 to Garza et al., which is also incorporated herein by reference. Upon delivery of stent 10 to the implantation site, the sheath is retracted, and the

stent is permitted to uncoil. The stent may be further expanded into position using a conventional balloon dilatation device, so that teeth 11 engage openings 13 to lock the stent in its deployed state.

Referring now to FIG. 2, illustrative apparatus constructed in accordance with the present invention is described. Apparatus 20 comprises flat sheet 21 of biocompatible material typically used in coiled sheet stents having upper surface 22 and lower surface 23. For clarity, the details of sheet 21 are omitted. Apparatus 20 preferably includes teeth 24 on longitudinal edge 25 and openings 26 on opposing longitudinal edge 27 that accept teeth 24 when the apparatus 20 is rolled into its deployed state. In accordance with the present invention a plurality of flaps 28 are affixed to upper surface 22 of sheet 21, and project upward from the sheet when unconstrained. Flaps 28 may be affixed to flat sheet 21 along marginal portion 29 using any suitable means, including welding, brazing or the use of a suitable biocompatible adhesive. Alternatively, flaps 28 may be individually attached to sheet 21 without marginal portion 29.

In FIG. 3, apparatus 20 is shown in a deployed configuration, wherein the sheet is rolled in the direction of arrow A about longitudinal edge 25 to form a tubular member. When rolled to the tubular configuration shown in FIG. 3, upper surface 22 forms lumen 30 into which flaps 28 project radially inward. Depending upon the length, shape, and composition of flaps 28, apparatus 20 may be configured to provide either a filter, flow regulator or valve, or an occlusive device.

Referring to FIG. 4A, an embodiment is depicted wherein flaps 28 are sized so that when the apparatus is arranged in its deployed configuration, edges 31 and tips 32 of the flaps overlap one another. In this case, flaps 28 extend over the entire cross-section of lumen 30. Preferably, the flaps are interdigitated in a manner similar to a camera-lens iris, so that each flap supports its neighboring flaps. In this embodiment, flaps 28 may be constructed of a fine mesh material, e.g., a stainless steel or nickel-titanium alloy, so that when deployed they form a filter. Thus, for example, apparatus 20 may be advantageously deployed in a blood vessel prior to a therapeutic procedure, such as angioplasty, or endarterectomy, to capture any frangible material liberated during the procedure. When employed as a blood filter, the mesh comprising flaps 28 may in addition be coated or impregnated with an anti-thrombogenic agent, such as heparin.

Alternatively, flaps 28 may be coated with a layer of fluid impermeable material, for example, polytetrafluoroethylene (PTFE) or polyurethane. In this case, when flaps 28 are deployed, they occlude flow through lumen 30. In addition, the flaps may be coated or impregnated with a thrombogenic agent, to cause further clotting off of the vessel or organ.

Referring to FIG. 4B, an alternative embodiment is shown in which tips 32′ of flaps 28′ do not overlap when the flaps are deployed. Instead, the flaps project from interior surface 22′ of the apparatus a distance less than the radius of the apparatus in the deployed configuration. Accordingly,

when flaps 28′ are deployed in lumen 30′, tips 32′ form an aperture 33′. In this case, flaps 28′ may again be coated with a fluid impermeable material, such as PTFE or urethane. Because aperture 33′ is smaller than the diameter of lumen 30′, flaps 28′ will create an impedance to flow passing through the apparatus, thereby providing a degree of passive flow regulation. The flow regulation is passive in the sense that it is the pressure differential created by the aperture that assists in regulating the flow, while flaps 28′ remain stationary.

In the alternative embodiment depicted in FIG. 4C, flaps 28″ are formed of a pliable plastic or polymeric material, either alone or coated over a flexible wire mesh. In this embodiment, the composition of flaps 28″ is selected so that the flaps form a valve that actively regulates flow through the vessel by moving. For example, flaps 28″ may be constructed to open, for example, when the pressure differential across the flaps exceeds a predetermined value. This aspect of the invention is shown by the dotted lines 28a in FIG. 4C. Alternatively, flaps 28″ may be biased in one direction to provide a one-way valve, whereby flaps 28″ open when flow is moving in one direction, but close off lumen 30″ when the flow moves in the opposite direction. Such an embodiment may be advantageously employed, for example, in the above-described patents to Nelson et al. and Wilk.

In FIGS. 5A and 5B, further alternative embodiments of the apparatus of the present invention are shown from an edge-on perspective. In FIG. 5A, apparatus 40 is described having flaps 41 that are

approximately trapezoidal in shape, as in the embodiment of FIG. 2, which as affixed to sheet 42. In FIG. 5A, however, the bases of the flaps are not joined to along their lengths to marginal portion 43. Instead, the bases include cut-out areas 44. The curved edges 45 of cut-out areas 44 approximate the curvature of the coiled sheet when it is rolled to its deployed to deployed configuration. Applicant expects that the inclusion of cut-out areas 44 in apparatus 40 will reduce the tendency of the flaps to cause the device to assume an out-of-round shape when deployed.

In apparatus 50 of FIG. 5B, flaps 51 are ellipsoidal in shape, and include cut-out areas 52 having curved edges 53 that approximate the curvature of the deployed apparatus. Flaps 51 are joined to sheet 54 by marginal portion 55. The ellipsoidal shape of flaps 51, like the trapezoidal shapes of flaps 28 and 41, are intended to be illustrative only. One of skill in the art of designing interventional implantable devices will readily recognize that the flaps used in a device constructed in accordance with the present invention could take any shape, so long as when the flaps are deployed they provide a beneficial therapeutic effect, e.g., as a filter, valve or occlusive device. For example, different ones of the plurality of flaps 28 may have different sizes, or may even comprise different materials.

Likewise, the precise number of flaps employed may vary depending upon the intended application. For smaller vessels, e.g., 3-5 mm, as few as two flaps may be used to provide a filter, valve or occlusive device. In larger vessels, e.g., up to 3 cm,

it may be desirable to employ a greater number of flaps. It is therefore to be understood that the use in the above-described embodiments of four and five flaps, respectively, is intended only for purposes of illustration, and that a greater or fewer number of flaps may be employed depending upon the specific application.

Referring now to FIGS. 6A to 6C, apparatus 20 of FIG. 2 is shown disposed within a delivery device in its contracted state. Delivery device 60 illustratively includes shaft 61 including a lumen for guidewire 62, inflatable balloon 63 and shoulder 64 of shaft 61 contacts the proximal edge of apparatus 20. Delivery device 60 further includes outer sheath 65 that retains apparatus 20 in the contracted state. Delivery device 60 may be constructed by modifying the delivery system described in the above-incorporated Sigwart patent, or U.S. Patent No. 4,665,918 to Garza et al., which is incorporated herein by reference.

As shown in FIG. 6B, apparatus 20 is contracted for delivery by bending flaps 28 so that they lie flat against interior surface 22, and then rolling flat sheet 21 from edge 25 toward edge 27. Apparatus 20 is then placed over inflatable balloon 63 of delivery device 60, and outer sheath 65 advanced to retain apparatus 20 in its contracted state. Alternatively, apparatus 20 may be directly wrapped around inflatable balloon 63 of shaft 61 with the outer sheath retracted, and the outer sheath is then advanced to retain apparatus 20 in position.

When apparatus 20 is rolled down to its contracted delivery state, flaps 28 offer little

resistance to rolling sheet 21 down tightly. When delivery device 60 is percutaneously and transluminally positioned at the site where the apparatus is to be deployed, outer sheath 65 is retracted proximally. As outer sheath 65 is retracted, shoulder 64 prevents proximal movement of apparatus 20.

As shown in FIG. 6C, when outer sheath 65 clears the proximal end of the coiled sheet, sheet 21 expands radially outward into contact with the interior of the wall of the vessel or body organ (not shown). Because flaps 28 are resiliently biased to project from interior surface 22 of sheet 21, they begin to project radially outward into lumen 30 as soon as coiled sheet assumes its expanded diameter. Next, inflatable balloon 63 is inflated to lock teeth 24 into engagement with openings 26 in edge 27 at a desired expanded diameter. Balloon 63 is then deflated and delivery device 60 is withdrawn from the patient's body. As delivery device 60 is retracted from within lumen 30 of apparatus 20, flaps 28 resiliently assume a position substantially orthogonal to the interior surface of the coiled sheet.

The methods and apparatus of the present invention have been described with reference to filtering, regulating flow within, or occluding blood vessels, and organs. The apparatus of the present invention is equally applicable to gastro-intestinal, respiratory, reproductive organ and urethral applications and elsewhere where is desirable to filter, regulate or occlude flow through an organ or vessel.

While preferred illustrative embodiments of the present invention are described above, it will be apparent to one skilled in the art that various changes and modifications may be made therein without departing from the invention and it is intended in the appended claims to cover all such changes and modifications which fall within the true spirit and scope of the invention.

What Is Claimed Is:

1. Apparatus implantable within a body vessel or organ, the apparatus comprising:

a tubular member having an interior surface defining a lumen, the tubular member comprising a rolled sheet having a longitudinal edge, the tubular member having a reduced diameter for transluminal delivery wherein the sheet is coiled to form overlapping turns, and an expanded diameter when deployed in the body vessel or organ; and

a plurality of flaps disposed from the interior surface of the tubular member, the flaps projecting radially inward into the lumen when the tubular member is in the deployed state.

2. The apparatus as defined in claim 1 wherein the plurality of flaps lie parallel to a longitudinal axis of the tubular member when the tubular member is contracted to the reduced diameter.

3. The apparatus as defined in claim 1 wherein the plurality of flaps comprise a fluid permeable mesh and span a cross-section of the lumen to form a filter.

4. The apparatus as defined in claim 3 further comprising a coating of an anti-thrombogenic agent disposed on the plurality of flaps.

5. The apparatus as defined in claim 1 wherein the plurality of flaps comprise a fluid

impermeable material and span a cross-section of the lumen to occlude the lumen.

6. The apparatus as defined in claim 5 further comprising an coating of a thrombogenic agent disposed on the plurality of flaps.

7. The apparatus as defined in claim 1 wherein each one of the plurality of flaps has a tip and comprises a fluid impermeable material, the plurality of flaps arranged so that they do not span a cross-section of the lumen, the tips of the plurality of flaps defining an aperture that regulates flow through the lumen.

8. The apparatus as defined in claim 1 wherein each one of the plurality of flaps comprises a resilient material capable of deflecting, the plurality of flaps forming a valve that opens when a pressure differential across the flaps exceeds a predetermined value.

9. The apparatus as defined in claim 1 wherein each one of the plurality of flaps comprises a resilient material capable of deflecting, the plurality of flaps forming a valve that opens when the flow of biological fluids moves in a first direction, and closes when the biological fluid moves in a second direction opposite to the first direction.

10. The apparatus as defined in claim 1 wherein the flaps have a trapezoidal shape.

11. The apparatus as defined in claim 1 wherein each one of the plurality of flaps includes cut-out areas near a point of attachment of the flap to the tubular member and a portion of the flap includes an edge that approximates a curvature of the tubular member when deployed.

12. The apparatus as defined in claim 1 wherein the sheet comprises a nickel-titanium alloy.

13. The apparatus as defined in claim 1 wherein the sheet has first and second longitudinal edges, a plurality of teeth arranged along the first longitudinal edge and a plurality of openings arranged along the second longitudinal edge, the plurality of teeth engaging the plurality of openings in the second longitudinal edge when the tubular member is deployed.

14. Apparatus implantable within a body vessel or organ to provide a therapeutic result, the apparatus comprising:

a tubular member having an interior surface defining a lumen, the tubular member formed by rolling a sheet having first and second longitudinal edges, a plurality of teeth arranged along the first longitudinal edge and a plurality of openings arranged along the second longitudinal edge, the tubular member having a contracted state of reduced diameter for transluminal delivery wherein the sheet is rolled to form a series of overlapping turns, and a deployed state of expanded diameter wherein the plurality of

teeth engage the plurality of openings in the second longitudinal edge; and

a plurality of flaps disposed from the interior surface of the tubular member, the flaps projecting radially inward into the lumen when the tubular member is in the deployed state.

15. The apparatus as defined in claim 14 wherein the plurality of flaps lie parallel to a longitudinal axis of the tubular member when the tubular member is in the contracted state.

16. The apparatus as defined in claim 14 wherein the vessel or organ forms a flowpath for a biological fluid, and wherein the plurality of flaps comprise a fluid permeable mesh and collectively span a cross-section of the lumen, so that when the apparatus is deployed in the flowpath, the apparatus provides a therapeutic result by filtering the biological fluid.

17. The apparatus as defined in claim 14 wherein the vessel or organ forms a flowpath for a biological fluid, and wherein the plurality of flaps comprise a fluid impermeable material and collectively span a cross-section of the lumen, so that when the apparatus is deployed in the flowpath, the apparatus provides a therapeutic result by occluding the flowpath of the biological fluid.

18. The apparatus as defined in claim 14 wherein the vessel or organ forms a flowpath for a biological fluid, and wherein each one of the plurality

of flaps has a tip and comprises a fluid impermeable material, the plurality of flaps arranged so that they collectively do not span a cross-section of the lumen, the tips of the plurality of flaps defining an aperture, so that when the apparatus is deployed in the flowpath, the apparatus provides a therapeutic result by reducing flow of the biological fluid.

19. The apparatus as defined in claim 14 wherein the vessel or organ forms a flowpath for a biological fluid, and wherein each one of the plurality of flaps comprises a resilient material capable of deflecting, the plurality of flaps forming a valve that opens when a pressure differential across the flaps exceeds a predetermined value, so that when the apparatus is deployed in the flowpath, the apparatus provides a therapeutic result by regulating flow of the biological fluid.

20. The apparatus as defined in claim 14 wherein the vessel or organ forms a flowpath for a biological fluid, and wherein each one of the plurality of flaps comprises a resilient material capable of deflecting, the plurality of flaps forming a valve that opens when the flow of biological fluids moves in a first direction, and closes when the biological fluid moves in a second direction opposite to the first direction, so that when the apparatus is deployed in the flowpath, the apparatus provides a therapeutic result by regulating flow of the biological fluid.

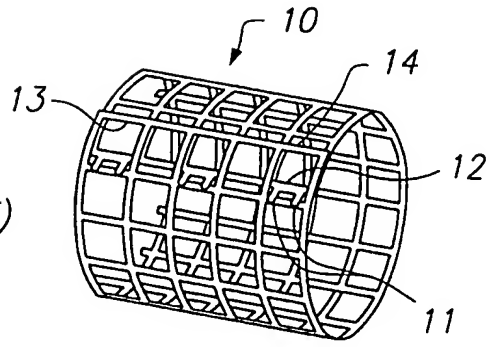

FIG. 1
(PRIOR ART)

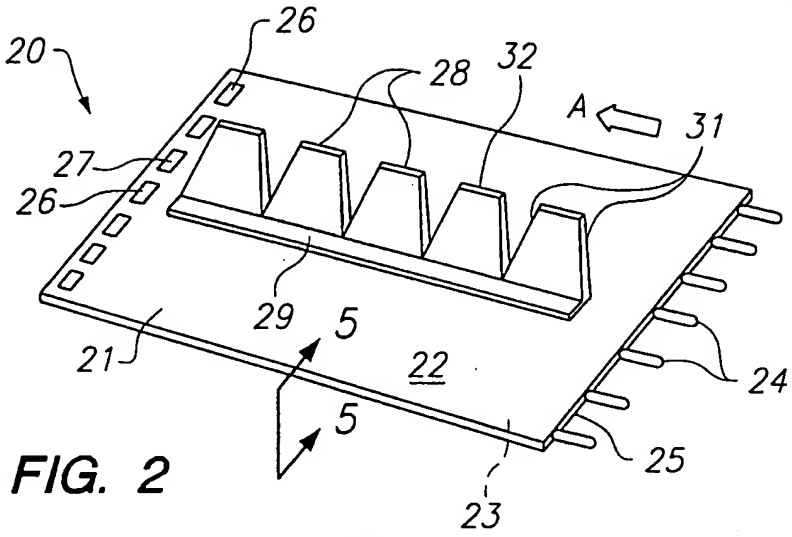

FIG. 2

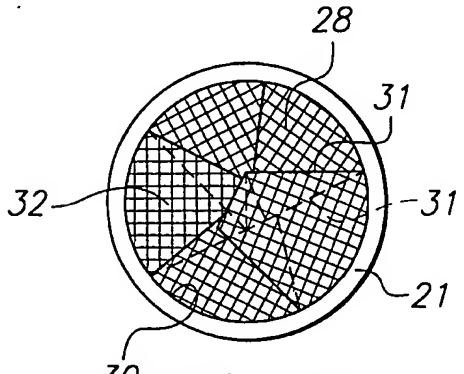

FIG. 4A

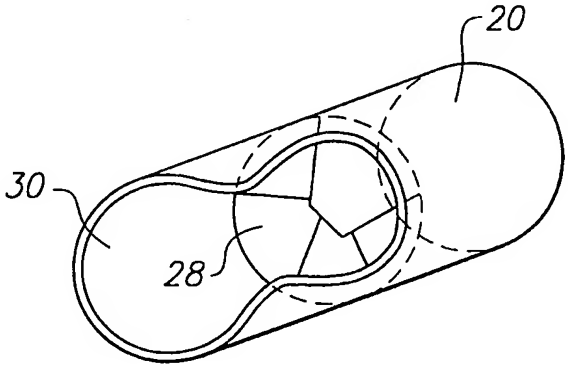

FIG. 3

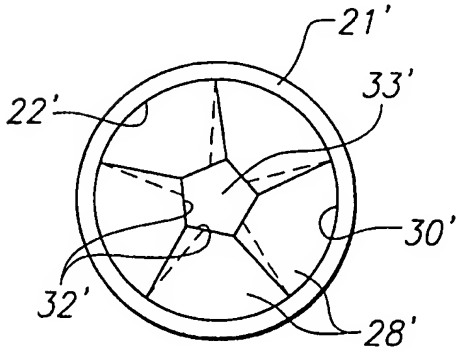

FIG. 4B

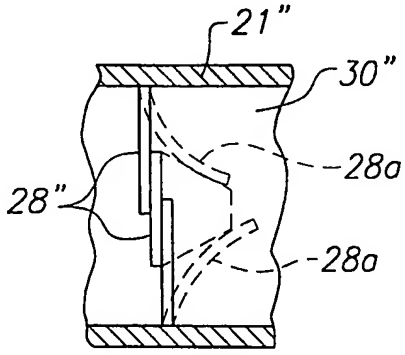

FIG. 4C

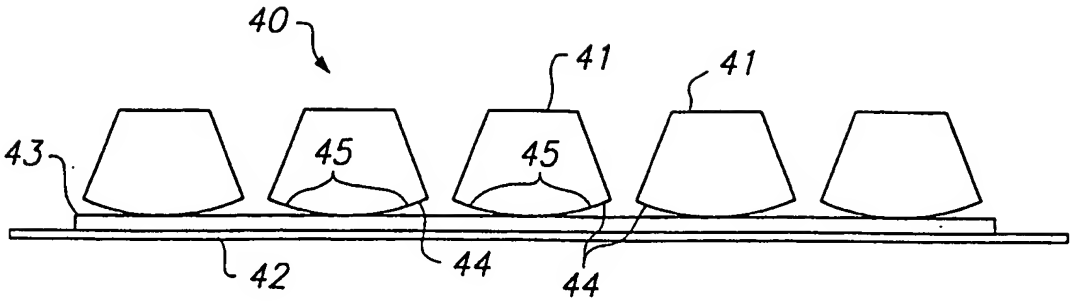

FIG. 5A

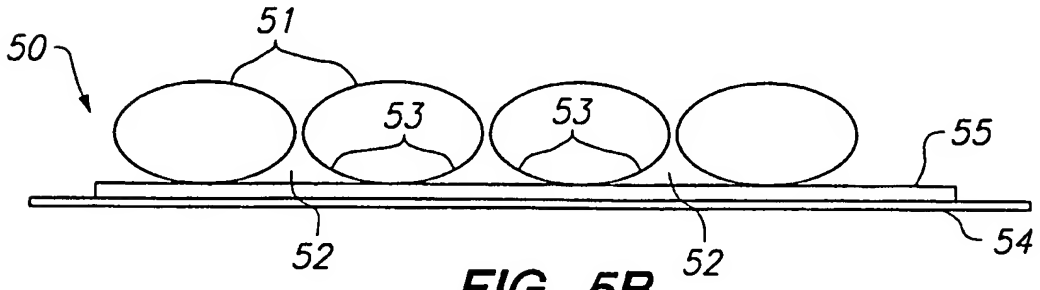

FIG. 5B

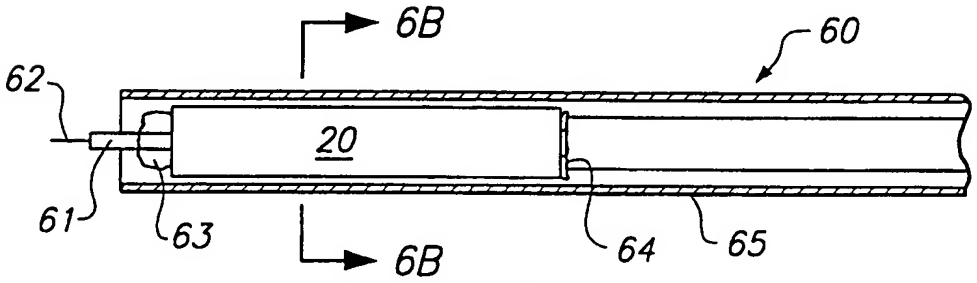

FIG. 6A

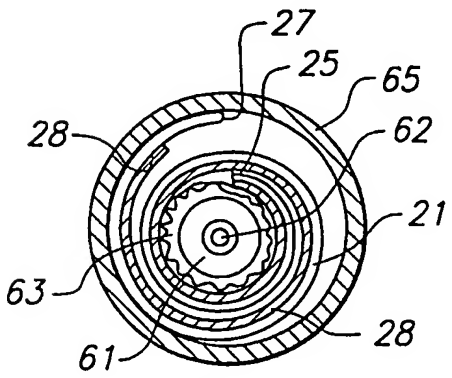

FIG. 6B

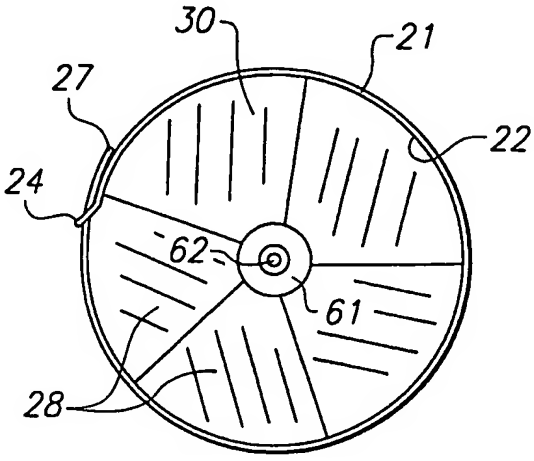

FIG. 6C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/19775

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61M 29/00
US CL :606/200
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/106, 190; 606/151, 191, 200; 623/1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P	US 5,800,525 A (BACHINSKI et al.) 01 September 1998, entire document.	1, 2, 7-9, 12
X	US 4,705,517 A (DiPISA, JR.) 10 November 1987, entire document.	1, 2, 5, 6
X	US 4,662,885 A (DiPISA, JR.) 05 May 1987, entire document.	1, 3, 4
X, E	US 5,824,046 A (SMITH et al.) 20 October 1998, entire document.	1, 10, 11

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search
17 DECEMBER 1998

Date of mailing of the international search report
20 JAN 1999

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